shall also be identified or discussed in the appropriate section of the labeling for the drug.

[44 FR 37462, June 26, 1979, as amended at 55 FR 11576, Mar. 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998]

§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under § 201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of § 314.126(b) of this chapter shall be submitted in writing as provided in § 314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or, if applicable, the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990, as amended at 70 FR 14980, Mar. 24, 2005]

§ 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

(a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §§ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the requirements set forth in the regulations, with the following exceptions:

(1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.

(2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

(3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

Effective	Revised labeling due	Drug class	Mail routing code
		BIOLOGICS	
Nov. 1, 1982	Nov. 1, 1980	Bacterial vaccines and antigens with no U.S. standard of potency.	HFB–240
Do	do	Skin test antigens	HFB–240
Nov. 1, 1982 [1]	Nov. 1,1980 [2]	Bacteral vaccines and toxoids with standards of potency.	HFB–240
Do	do	Viral and rickettsial vaccines	HFB–240
Do	do	Allergenic extracts	HFB–240
Do	do	Blood and blood derivatives	HFB–240
		NEW DRUGS AND ANTIBIOTIC DRUGS	
Nov. 1, 1982	Nov. 1, 1980	Antiarrhythmics	HFD–110
Do	do	Replenishers and regulators of electrolytes and water balance	HFD–110, HFD–510, and HFD–160
Do	do	Anticonvulsants	HFD–120
Do	do	Adrenal corticosteroids	HFD–510 and HFD–150
Do	do	Aminoglycosides	HFD–520
Do	do	Scabicides	Do.
Do	do	Pediculicides	Do.
Do	do	General anesthetics	HFD–160
Dec. 1, 1982	Dec. 1, 1980	Antivirals	HFD–520
Do	do	Dermatologics	Do.
Jan. 1, 1983	Jan. 1, 1981	Glaucoma ophthalmics	HFD–520
Do	do	Topical otics	Do.

Effective	Revised labeling due	Drug class	Mail routing code
Feb. 1, 1983	Feb. 1, 1981	Antispasmodics	HFD–110
Do	do	Anticholinergics	Do.
Do	do	Diuretics	Do.
Do	do	Narcotic antagonists	HFD–120
Do	do	Alcohol antagonists	Do.
Do	do	Antipsychotics/antimanics	Do.
Do	do	Androgens	HFD–510
Do	do	Anabolic steroids	Do.
Do	do	Hyperlipidemia	Do.
Do	do	Anthelmintics	HFD–520
Do	do	Antigout	HFD–150
Mar. 1, 1983	Mar. 1, 1981	Vaginal antibiotics	HFD–520
Apr. 1, 1983	Apr. 1, 1981	Cephalosporins	HFD–520
May 1, 1983	May 1, 1981	General analgesics	HFD–120
Do	do	Anterior pituitary hormones	HFD–510
Do	do	Hypothalamic hormones	Do.
Do	do	Progestins	Do.
Do	do	Mydriatic ophthalmics	HFD–520
Do	do	Cycloplegic ophthalmics	Do.
Do	do	Radiopharmaceuticals, diagnostic	HFD–150
Do	do	Radiopharmaceuticals, therapeutic	Do.
Do	do	Contrast agents diagnostic radiopaque	Do.
Do	do	Local anesthetics	HFD–160
Do	do	Antihistamines	Do.
June 1, 1983	June 1, 1981	Antifungals	HFD–520
July 1, 1983	July 1, 1981	Antidiarrheals	HFD–110
Do	do	Cardiac glycosides	Do.
Do	do	Sedatives	HFD–120
Do	do	Hypnotics	Do.
Do	do	Tetracyclines	HFD–520
Aug. 1, 1983	Aug. 1, 1981	Calcium metabolism	HFD–510
Do	do	Vitamins and minerals	Do.
Do	do	Antiinfective ophthalmics	HFD–520
Do	do	Antiinflammatory ophthalmics	Do.
Sept. 1, 1983	Sept. 1, 1981	Antihypertensives	HFD–110
Do	do	Drugs indicated for extrapyramidal movement disorders	HFD–120
Do	do	Antiprotozoals	HFD–520
Oct. 1, 1983	Oct. 1, 1981	Penicillins	HFD–520
Nov. 1, 1983	Nov. 1, 1981	Blood glucose regulators (except sulfonylureas)	HFD–510
Oct. 9, 1984	July 10, 1984	Sulfonylurea blood glucose regulators	HFN–130
Nov. 1, 1983	Nov. 1, 1981	Drugs indicated for parenteral nutrition	HFD–510 and HFD–160
Do	do	Drugs indicated for enteral nutrition	Do.
Do	do	Miscellaneous ophthalmics	HFD–520
Do	do	Immunomodulators	HFD–150
Dec. 1, 1983	Dec. 1, 1981	Anticoagulants	HFD–110
Do	do	Thrombolytics	Do.
Do	do	Drugs indicated for acid peptic disorders	Do.
Do	do	Antidepressants	HFD–120
Do	do	Drugs indicated for skeletal muscle hyperactivity	Do.
Do	do	Sulfonamides and related sulfa compounds	HFD–520
Do	do	Dental preparations	HFD–160
Jan. 1, 1984	Jan. 1, 1982	Miscellaneous antibacterials	HFD–520
Feb. 1, 1984	Feb. 1, 1982	Drugs indicated for infertility	HFD–510
Do	do	Thyroids	Do.
Do	do	Antithyroids	Do.
Do	do	Polymyxins	HFD–520
Do	do	Antineoplastics	HFD–150
Mar. 1, 1984	Mar. 1, 1982	Urinary tract stimulants	HFD–110
Do	do	Urinary tract relaxants	Do.
Do	do	Antimigraine	HFD–120
		Antimycobacterials (including antileprosy)	HFD–520
Do	do	Adjuncts to anethesia	HFD–160
Apr. 1, 1984	Apr. 1, 1982	Antianginals	HFD–110
Do	do	Laxatives	Do.
Do	do	CNS stimulants	HFD–120
Do	do	Anorexiants	Do.
Do	do	Chloramphenicol and derivatives	HFD–520
May 1, 1984	May 1, 1982	Drugs indicated for vertigo/motion sickness/vomiting	HFD–120
Do	do	Antidiuretics	HFD–510
Do	do	Contraceptives	Do.
Do	do	Macrolides	HFD–520
Do	do	Lincosamides	Do.
Do	do	Antiarthritics	HFD–150

Effective	Revised labeling due	Drug class	Mail routing code
Do	.....do	Antitussives	HFD–160
Do	.....do	Expectorants	Do.
Do	.....do	Inhalants	Do.
June 1, 1984	June 1, 1982	Urinary tract antiseptics	HFD–520
July 1, 1984 ..	July 1, 1982 ..	Chelating agents/heavy metal antagonists	HFD–110
Do	.....do	All other gastrointestinal drugs	HFD–110
Do	.....do	Antianxiety	HFD–120
Do	.....do	Drugs indicated for myasthenia gravis	HFD–120
Do	.....do	All other antiinfective drugs	HFD–520
Do	.....do	Bronchodilators/antiasthmatics	HFD–160
Aug. 1, 1984	Aug. 1, 1982	Estrogens	HFD–510
Do	.....do	Uterine stimulants	HFD–510
Do	.....do	Uterine relaxants	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock	HFD–110
Oct. 1, 1984 ..	Oct. 1, 1982	All other cardiac drugs	HFD–110
Do	.....do	Nasal decongestants	HFD–160
Nov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	

[1] Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).
[2] Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term *principal display panel,* as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious ''principal display panel'' such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

(a) The principal display panel of an over-the-counter drug in package form